DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

D13233

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

March 27, 1997

WARNING LETTER
CHI-23-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Vernon Loucks Jr., President
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL

Dear Mr. Loucks:

During an inspection of the McGaw Park, Illinois facility of the Renal Division of Baxter Healthcare from November 13, 1996 to February 14, 1997, Investigators Michael Lang and Tamara Alicea determined your firm manufactures hemodialysis machines. Hemodialysis machines are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed the devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice Regulations (GMP) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to determine whether complaints were due to actual failures of a device to meet performance specifications. For example, Complaints A96010302, A96062001, A96062001, A96071202, A96081402, A96081502, and A96092703 were not evaluated to determine whether the device actually failed. If a complaint is confirmed to have been an actual failure, a failure investigation must be performed.

2. Failure to review, evaluate, and maintain all written or oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness or performance of a device. For example, service reports of conductivity cell replacement (e.g. service call reports 151522 and 151824) were not reviewed, evaluated or maintained by the designated complaint handling unit.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the enclosed FDA

483 issued to Mr. Roberto Perez at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that Mr. Richard Thuma submitted to this office a response, dated February 20, 1997, concerning our investigator's observations noted on the Form FDA 483. It appears that the response is adequate, therefore no submissions for premarket clearance will be withheld for GMP reasons.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a later comprehensive follow-up inspection, and may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide the current status of your firm's promised corrective actions to Stephen Eich, Compliance Officer.

Sincerely,

/S/

Raymond V. Mlecko
District Director

Enclosure

cc: Mr. Donald W. Joseph
Group Vice President
President/Renal Division

cc: Roberto Perez
President/Global Operations

cc: Richard S. Thuma, Vice President
Quality and Regulatory Affairs Renal
Baxter Healthcare Corp.
1620 Waukegan Road
McGaw Park, IL 60085